

### **Remarks**

Applicant respectfully requests reconsideration and allowance of this application in view of the amendments above and the following comments. Applicants respectfully submit that the amendments are fairly based on the specification and respectfully request their entry.

### **Specification-Objections**

Applicants have amended the Specification above at pages 52 and 143 to correct typographical errors, in accordance with the Examiner's suggestions. Applicants respectfully request that the objections to the Specification be withdrawn.

### **Abstract**

Applicants have amended the Abstract above to define the term "LCP". Support for the definition inserted can be found in the Specification at page 4, lines 18-19 and page 5, line 31 to page 6, line 2. Applicants respectfully request the objection to the Abstract be withdrawn.

### **Claim-Objections**

Claim 1 is objected to for reciting the phrase "... diseases involving cell-cell adhesion process . . . ." Applicants have amended claim 1 above to recite "... diseases involving cell-cell adhesion processes . . . ." in accordance with the Examiner's suggestion. Applicants respectfully request that the objection to claim 1 be withdrawn.

Claim 2 is objected to under 37 CFR 1.75(c), as being of improper form for failing to further limit the subject matter of the base claim. Applicants are grateful to the Examiner for directing their attention to this and in response, have cancelled claim 2 above. Thus, the basis for the objection has been eliminated and therefore, the objection should be withdrawn.

### **35 U.S.C. § 101 REJECTION OF CLAIMS 1-12, 32, 33, & 39**

Claims 1-12, 32, 33 and 39 are rejected under 35 USC § 101 for, in the Examiner's view, lacking utility. More specifically, the Examiner asserts that the claimed invention is not supported by a deduced or an established utility. Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection Applicants respectfully submit that the claimed nucleic acid can be used to encode proteins (i.e. human LCP) which, through shared structural features with the LCCL domain containing gene family have potential

therapeutic as well as diagnostic roles in neurological and developmental disorders and diseases involving cell-cell adhesion processes. The nucleic acids also have demonstrated utility as PCR primers/probes (e.g. Example 2, pages 138-140, claims 3-6) that can be used in microarrays (claim 7) and have utility in vectors (claims 9 and Example 4) for transforming host cells (claim 11) which in turn can be cultured to produce polypeptides (claim 12, Example 4). Furthermore, the nucleic acids and polypeptides of the claimed invention have utility in diagnosis (claim 32) and in the treatment of disease (claim 33).

Because the claimed nucleic acid sequences of the instant application share the same structural features as other members of the LCCL domain containing gene family (FIG,1), Applicants respectfully submit that the claimed invention is similarly useful. According to the Federal Circuit, “[t]he threshold of utility is not high: An invention is ‘useful’ under section 101 if it is capable of providing **some identifiable benefit**.” *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (emphasis added). Therefore, Applicants respectfully request that the above rejection be withdrawn.

### **35 U.S.C. § 112, 2<sup>nd</sup> PARAGRAPH REJECTION OF CLAIMS 1-12, 32, 33, & 39**

Claims 1-12, 32, 33 and 39 are rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner objects to use of the phrase “conservative amino acid substitutions” as it appears in claim 1, as

vague, indefinite and undefined in the specification. Additionally, the Examiner objects to use of the phrase “or progeny thereof” as it appears in claim 11, as indefinite. Finally, the Examiner objects to the recitations: “SEQ ID NO: 2, 1113” and “SEQ ID NO: 3, 1114” as they appear in claim 1 and “SEQ ID NO: 4, 6 or 1115” as it appears in claim 4. In view of the amendments above, Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection, Applicants have amended claim 1 above to delete the term “conservative amino acid substitutions”. Therefore, Applicants submit that the basis for the above rejection of claims 1, 2-12, 32, 33, and 39 with respect to the term “conservative amino acid substitutions”, has been eliminated.

Applicants have also amended claim 1 to delete the recitations “SEQ ID NO: 2, 1113” and “SEQ ID NO: 3, 1114” and substitute - - SEQ ID NO: 2 or SEQ ID NO: 1113 - - and - - SEQ ID NO: 3 or SEQ ID NO: 1114 - - as suggested by the Examiner. Similarly, claim 4 has been amended above to delete the recitation “SEQ ID NO: 4, 6 or 1115”.

Finally, claim 11 has been amended above to clarify the objectionable phrase “or the progeny thereof” to read - - or the progeny of said host cell - - . In view of the above amendments to the claims Applicants respectfully submit that the basis for the above rejection has been eliminated. Thus, it is respectfully requested that the 35 U.S.C. § 112, second paragraph rejection be withdrawn.

**35 U.S.C. § 112, FIRST PARAGRAPH REJECTION OF CLAIMS 1-12, 32, 33 & 39**

Claims 1-12, 32, 33 and 39 are rejected under 35 USC § 112, first paragraph as non-enabled. Specifically, the Examiner appears to object to the phrase “with conservative amino acid substitutions”, which the Examiner appears to identify as resulting in the impermissible broadening the scope of the claims beyond the ability of the skilled artisan to make and use, due to the enormous number of possible amino acid modifications. Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection Applicants have amended claim 1 above, to delete the phrase “with conservative amino acid substitutions”. As a result, claim 1 is now limited to the sequences or complete compliment sequences of SEQ ID NO: 2 or SEQ ID NO: 1113 or SEQ ID NO: 3 or SEQ ID NO: 1114, or to sequences at least 90% identical. Thus, the phrase that the Examiner identified as resulting in the impermissible broadening the scope of the claims, due to the enormous number of possible amino acid modifications, has now been eliminated from claim 1. Therefore, Applicant respectfully submit that the basis for the above rejection, as it relates claim 1 and the claims directly dependent therefrom, has been eliminated.

In further response to the above rejection and to the amendments made to claim 1, Applicants have inserted new claims 48 and 49, in order to further limit subject matter

originally covered in claim 1, as amended. New claims 48 and 49 respectively recite sequences encoding polypeptides at least 95% and 99% identical in sequence to SEQ ID NO: 2 or SEQ ID NO: 1113 or SEQ ID NO: 3 or SEQ ID NO: 1114. New claims 48 and 49 are fully supported by the original claims and the specification, particularly at page 19. Applicants respectfully point out that new claims 48 and 49 are free from the phrase “with conservative amino acid substitutions”.

Claims 1-12, 32, 33 and 39 are further rejected under 35 USC § 112, first paragraph. Specifically, the Examiner objects to what he views as a lack of description sufficient to convey to one skilled in the art that the inventor had possession of the invention, at the time of filing. Applicants respectfully traverse this rejection for the reasons set forth below.

In response to the above rejection, Applicant point out that claim 1 has been amended above to more clearly set forth the claimed invention. Applicants have deleted the phrase “with conservative amino acid substitutions”, which the Examiner appeared found objectionable. As discussed above, the Examiner to identified the phrase broadening the scope of the claims beyond the ability of the skilled artisan to make and use, due to the enormous number of possible amino acid modifications. Applicants respectfully submit that in view of the above amendments to claim 1 and the insertion of new claims 48 and 49, as supported by the original claims and specification, one of ordinary skill in the art can clearly determine that Applicants were in possession of the invention at the time of filing. Therefore, reconsideration is respectfully requested.

### **35 U.S.C. 102(b) REJECTION OF CLAIM 4**

Claims 1-2 are rejected under 35 U.S.C. § 102(b) as anticipated by Birren et al, 2000 (hereinafter "Birren") or Rosteck et al, 2000 (hereinafter "Rosteck") or Hillier et al, 1995 (hereinafter "Hillier") Specifically, the Examiner asserts that the cited references disclose polynucleotides having 100% identity with SEQ ID NO: 4, SEQ ID NO: 6 and SEQ ID NO: 1115. Applicants respectfully traverse this rejection for the reasons set forth below.

Applicants respectfully point out that claim 4 has been amended above to "A nucleic acid probe, comprising: (a) the nucleic acid of claim 1." The recitations referring to SEQ ID NO: 4, SEQ ID NO: 6 and SEQ ID NO: 1115, have been deleted from claim 4. Therefore, Applicants submit that claim 4, as amended above, cannot be anticipated by the Birren, Rosteck or Hillier references as set forth above. Thus, Applicants respectfully request that the above rejection be withdrawn.

### **35 U.S.C. § 103(a) REJECTION OF CLAIMS 5-7**

Claims 5-7 are rejected under 35, U.S.C. § 103(a) as being unpatentable over Birren et al, 2000 (hereinafter "Birren") or Rosteck et al, 2000 (hereinafter "Rosteck") or Hillier et al, 1995 (hereinafter "Hillier") or Penn et al, 2000 (hereinafter "Penn") in view of Old et al, 1985 (hereinafter "Old") and Schena et al, 1996 (hereinafter "Schena"). Specifically, the

Examiner asserts that Birren, Rosteck, Hillier or Penn disclose the polynucleotides of claims 4, 5, 6 and 7 but, do not teach the "nucleotides detectably labeled, attached to a substrate, or in a microarray." However, the Examiner continues, stating that Old supplies and suggests methods of labeling the nucleotides of Birren, Rosteck, Hillier or Penn and that Schena supplies and suggests methods of attaching said nucleotides to a substrate and use of said nucleotides in a microarray. The Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of invention, to label or attach the nucleotides of Birren, Rosteck, Hillier or Penn, to a substrate and use said nucleotides in a microarray and that one would have been motivated to do so. Applicants respectfully traverse this rejection for the reasons set forth below.

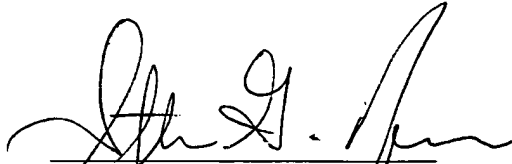
In response to the above rejection, Applicants submit that as argued above under the 35 U.S.C. § 102(b) rejection, the Birren, Rosteck, Hillier and Penn references do not teach or disclose the nucleic acid of claim 1, to which claim 4 is now limited. Claims 5, 6 and 7 are also limited to the nucleic acid of claim 1 by virtue of their direct dependence from claim 4. Therefore, claims 5, 6 and 7 no longer claim the nucleotides of the Birren, Rosteck, Hillier and Penn references. Thus, the basis for the above rejection has been eliminated and consequently, a *prima facie* case of obviousness has not been established for claims 5, 6 and 7 over the cited combination of references.

In view of the above deficiencies of the cited references, alone or in combination, the presently claimed invention is patentably non-obvious over the prior art. Thus, it is respectfully requested that the above rejections be reconsidered and withdrawn.



Early and favorable action is earnestly solicited.

Respectfully submitted,



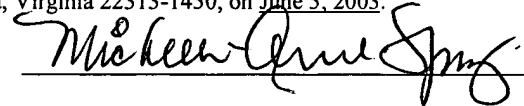
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on June 5, 2003.

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